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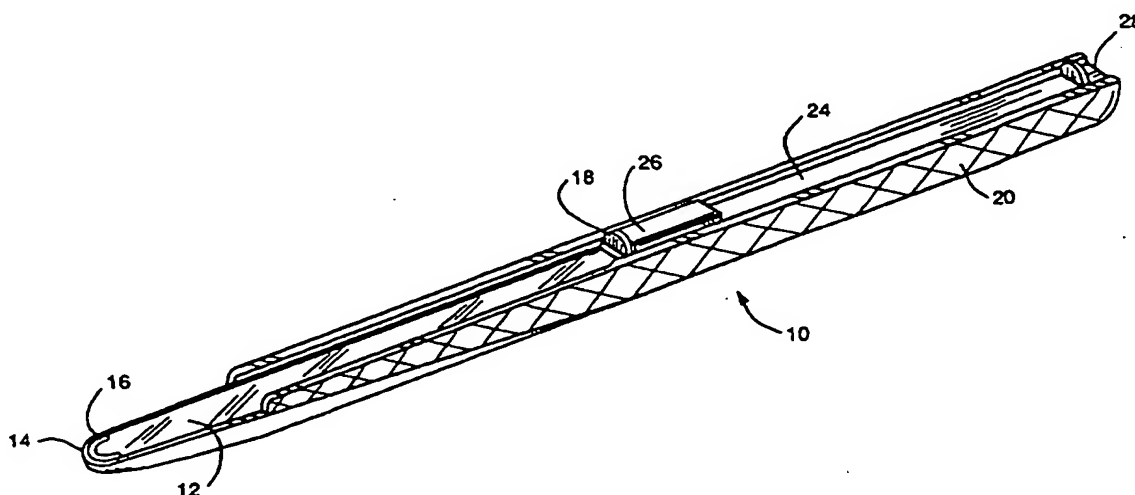
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(21) International Application Number: <b>PCT/US96/15030</b> (22) International Filing Date: <b>19 September 1996 (19.09.96)</b>  (30) Priority Data: 08/537,303 29 September 1995 (29.09.95) US 08/686,333 25 July 1996 (25.07.96) US  (71) Applicant: <b>MAXILON LABORATORIES, INC. [US/US]; 98 Ridge Road, Hollis, NH 03049 (US).</b> (72) Inventors: <b>ALTOBELLI, David, E.; 74 Crestwood Drive, Hollis, NH 03049 (US). EBNER, Peter, R.; 98 Ridge Road, Hollis, NH 03049 (US).</b> (74) Agent: <b>SOLOWAY, Norman, P.; Hayes, Soloway, Hennessey, Grossman &amp; Hage, 175 Canal Street, Manchester, NH 03101 (US).</b>		(81) Designated States: <b>AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</b>  <b>Published</b> <i>With international search report.</i>

(54) Title: **APPARATUS AND METHOD FOR HARVESTING BONE**



(57) Abstract

An instrument for harvesting bone comprised of an elongate body (20) having a hollow (32), and a proximal end and a distal end communicating with one another through the hollow. A loop shaped blade (12) having a curved cutting edge (14) adjacent to a curved aperture (16) or cutting or abrading bone is located at the distal end of the instrument. The cut or abraded bone moves through the aperture and into the hollow for storage. The retractable blade provides access to the stored bone for manipulation as needed, and a plunger (24) in the handle advances the bone for placement in the recipient site.

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## 1     **APPARATUS AND METHOD FOR HARVESTING BONE**

2           The present invention relates to the field of surgery. The invention has  
3 particular utility in connection with the removal and collection of bone from  
4 the surface of one or more donor sites, and the preparation and placement of  
5 the autogenous bone material at a second location in the patient., e.g. for use in  
6 grafting bone to osseous deficiencies, such as periodontal and dentoalveolar  
7 defects, bone deficiencies around dental implants, and numerous orthopedic  
8 applications that require grafting.

9           Many reconstructive procedures used in medicine and dentistry involve  
10 the manipulation and healing of bones. Such procedures may involve changes  
11 in the position, orientation, shape and size of skeletal structures. A problem  
12 that is commonly encountered during such procedures is a lack of bone graft  
13 material. Bone graft material may be used in several applications, such as to  
14 fill between sections of bone that have been repositioned, to change surface  
15 geometry, or to add bone to an area that is deficient, such as in conjunction  
16 with periodontal surgery or dental implants in the patients' jaws.

17           The need to harvest small bone grafts from intraoral sites has been  
18 common in periodontal surgery to restore bone defects around teeth. In the  
19 case of dental implant surgery, bone grafts may be needed to augment atrophic  
20 alveolar ridges of the maxilla and/or mandible and the sinus floor to increase  
21 the dimension of these bone sites to accommodate and totally cover the  
22 endosseous portion of implant fixtures. Bone grafts also are used in  
23 conjunction with guided tissue regeneration, a technique that uses a membrane  
24 to isolate hard tissue from soft tissue sites and potentiate hard tissue healing.

25           Presently, it is often difficult to harvest adequate amounts of  
26 autogenous bone from intraoral sites. Therefore, clinicians often rely on non-  
27 autogenous sources of graft material, such as bone from cadaver sources  
28 (homologous or allogenic grafts), animal sources (heterogenous or xenogeneic  
29 grafts), or synthetic bone substitutes. However, healing of non-autogenous  
30 material grafts is not as extensive or predictable as healing of autogeneous

1 bone obtained directly from the patient; plus there is the additional cost of  
2 such non-autogenous graft materials which can be significant.

3 Clinicians use several techniques to remove bone for grafting for  
4 intraoral procedures. In one such technique rotary instruments, such as side  
5 cutting burrs or trephines, are used to remove a piece or section of cortical  
6 bone from a local intraoral site in the maxilla or mandible. The cortical bone  
7 is often morsalized into a particulate form, either manually with a rongeur like  
8 instrument or in a bone mill. The particulate bone is then combined with  
9 blood to form an osseous coagulum, which is then positioned and packed into  
10 the osseous defect around the teeth or implant. See Robinson, R.E. "Osseous  
11 Coagulum for Bone Induction", J. Periodontology 40:503(1969). Suction  
12 devices with filters have been fabricated and manufactured to collect the bone  
13 dust from rotary instruments. See Hutchinson, RA "Utilization of an Osseous  
14 Coagulum Collection Filter", J. Periodontology 44:668(1973). See also  
15 Goldman, et al, "Periodontal Therapy", pp 994-1005, C.V. Mosby Co., (1980);  
16 and Haggarty, et al., "Autogeneous Bone Grafts: A Revolution in the  
17 Treatment of Vertical Bone Defects", J. Periodontology 42:626(1971). While  
18 such techniques are widely used by clinicians, the techniques have limitations,  
19 since sites to harvest sections of intraoral bone are limited in number and  
20 extent because of limited intraoral access, proximity to tooth roots, nerve  
21 structures and sinus cavities, and thin plates of bone.

22 Other techniques for harvesting bone include using chisels or  
23 osteotomes to remove and manually collect shavings from the surface. These  
24 instruments must be very sharp and the process is often awkward and time  
25 consuming. Other manual instruments such as bone files and rasps also  
26 remove bone. However, the efficiency of cutting and the ability to use the  
27 removed bone is greatly limited. Another technique is to collect bone dust  
28 generated by twist drills or taps used to prepare the sites for implant  
29 placement. However, much of the bone material may be lost while the site is

1 being irrigated to cool the cutting instrument. When larger amounts of bone  
2 are needed for major reconstructive procedures, other sites such as the hip  
3 (anterior or posterior ilium), tibia, ribs, or the calvarium often are used.  
4 However, using such other sites necessitates a second surgical site, which may  
5 require postoperative hospitalization, and thus is less amenable, e.g. in the case  
6 of an out-patient dental procedure.

7 Various surgical devices have been proposed and/or are in use to  
8 harvest bone marrow samples for biopsy or devices such as rongeurs or bone  
9 cutters or punches to remove sections or convex edges of bone. Surgical  
10 devices also are in use in arthroscopy and endoscopy for cutting or drilling  
11 bone or tissue and removing the tissue fragments. Ultrasonic devices to cut  
12 bone also are in use; however, such devices require the removal of the irrigant  
13 and debris liberated by the apparatus. Each of these methods and/or devices,  
14 however, suffers from one or more deficiencies as applied to the collection of  
15 bone for grafting.

16 Yet other patented devices have been proposed; each of these,  
17 however, suffers from one or more deficiencies:

18 U.S. Patent Nos. 5,403,317 and 5,269,785 to Bonutti show a method  
19 and apparatus for the percutaneous cutting and removal of tissue fragments  
20 from human. The Bonutti device removes the tissue fragments by suction,  
21 where it can be collected and then placed elsewhere in the patient from where  
22 originally obtained. Bonutti employs a flexible drill, and suction to remove  
23 the debris to an externally placed collection reservoir, where it is compressed  
24 before being replaced into the patient.

25 U.S. Patent No. 2,526,662 to Hipps discloses a bone meal extractor  
26 apparatus for mechanically removing bone meal from a donor bone site  
27 through a small percutaneous site using a drill. The drill shavings, which  
28 comprise primarily sub-surface bone, are then evacuated into an open cut that  
29 the drill passes through, for collection.

1 U.S. Patent No. 4,798,213 to Doppelt teaches a device for obtaining a  
2 bone biopsy for diagnosis of various bone diseases. The Doppelt device is  
3 intended to remove a core of bone using a tubular drill, while maintaining the  
4 architecture of the tissue. The sample is obtained from the marrow space and  
5 not intended from re-implantation.

6 U.S. Patent No. 5,133,359 to Kedem shows a hard tissue biopsy  
7 instrument in which samples are taken using a rotatably driven hollow needle.

8 U.S. Patent No. 4,366,822 to Altshuler discloses a method and  
9 apparatus for bone marrow cell separation and analysis. The Altshuler  
10 apparatus collects bone marrow cells in a filtration chamber on a filter  
11 interposed between a needle directed into the bone marrow site and an  
12 aspirator or vacuum source, i.e. using negative pressure to withdrawal marrow  
13 cells through a needle.

14 U.S. Patent No. 5,052,411 to Schoolman teaches, a vacuum barrier  
15 attachment for shielding the operator of a medical tool from harmful aerosols  
16 and blood, etc. created by drilling, sawing types of actions, etc. The  
17 Schoolman device requires vacuum and is not intended for harvesting tissue  
18 for re-implantation.

19 U.S. Patent No. 4,722,338 to Wright et al discloses a device instrument  
20 for removing bone which uses a shearing action similar to a rongeur to cut  
21 bone, with means for collecting fragments of bone as they are removed. The  
22 Wright et al device reportedly is used mainly for the removal of projections or  
23 edges of bone using a shearing mechanism without the intent of harvesting the  
24 bone for grafting.

25 U.S. Patent No. 4,994,024 to Falk teaches an arthroscopy hook-  
26 clippers device that allow the unobstructed removal of tissue or bone with  
27 removal of the fragments by suction. The Falk device is intended for  
28 arthroscopy applications and with the removal of projections of tissue or bone  
29 and not specifically for the harvest of tissue for grafting.

1 Yet other prior art devices are disclosed in U.S. Patent No. 4,466,429  
2 to Loscher et al and U.S. Patent No. 4,844,064 to Thimsen et al.  
3 It is thus a primary object of the present invention to provide an improved  
4 method and device for removing and harvesting bone or the like, and  
5 delivering the bone to a second site, which overcomes the aforesaid and other  
6 disadvantages of the prior art. A more specific object of the present invention  
7 is to provide an improved method and device for directly, percutaneously or  
8 permucosally removing and collecting bone from one or more donor sites, and  
9 for temporarily storing the collected bone and preparing the bone for delivery  
10 to a pre-selected recipient site.

11 The invention is directed to a hand-held surgical instrument for the  
12 cutting, removal, and storage of bone surface shavings for use as autogenous  
13 bone grafts. The instrument is comprised of a blade mounted in a handle for  
14 holding and supporting said blade. The blade has a cutting structure adjacent  
15 its distal end in the form of a sharpened loop. The loop's wedge shaped cross-  
16 section is defined proximally by a perpendicular curved aperture through the  
17 blade, and distally by a ground and honed relief. In the preferred form, the  
18 handle cooperates to provide a storage space adjacent the distal end of the  
19 blade for receiving harvested bone from the cutting structure. This manual  
20 instrument is held at an acute angle to the bone, and with minimal downward  
21 pressure, is drawn across the bone surface to cut and collect a thin shaving of  
22 bone. The blade is preferably retractable to allow the clinician access to the  
23 harvested material. A plunger is incorporated into the handle to serve both as  
24 a locking mechanism to secure the blade and as a means to advance and  
25 consolidate the bone in the distal aspect of the instrument.

26 Fig. 1 is a perspective view of an associated instrument embodying the  
27 invention.

28 Fig. 2 shows side (2B), top (2A, 2E, 2F), bottom (2C), and sectional  
29 (2D) views of the handle.

1           Fig. 3. shows side (3B), top (3A), bottom (3C), and sectional (3D)  
2 views of the plunger.

3           Fig. 4 shows top (4A), side (4B), and end (4C) view of the blade.

4           Fig. 5 shows enlarged top (5A) and sectional (5B) views of the distal  
5 (cutting) end of the blade.

6           Fig. 6. is a diagrammatic illustration of the various angles involved in  
7 the cutting operation of the blade.

8           Fig. 7. illustrates the use of the instrument to collect (7A), mix (7B)  
9 and apply (7C) bone shavings.

10          Figs. 8A-8F show modified versions of handle and bone collection  
11 systems.

12          The general arrangement of the elements is shown most clearly in Fig.  
13 1. This shows the assembly comprising the blade 12, the cutting edge 14, and  
14 aperture 16, a blade tab 18, the handle 20, a plunger 24, a lock button 26, and a  
15 plunger tab 28, all of which are discussed in more detail hereinafter.

16          Referring now to Figs. 4, there is shown a construction of a preferred  
17 form of the blade of the invention. This cutting structure is comprised of a  
18 loop shaped cutting geometry formed on the distal end of the cutting blade 12.  
19 The curved structure of the preferred embodiment is a semi-circular cutting  
20 edge 14 formed by perforating the distal end of the blade 12 with a semi-  
21 circular hole 16. The back surface of the blade, i.e., the surface away from the  
22 one adjacent the bone structure, is preferably relieved at 13 between its edges  
23 so that the depth of the hole adjacent the cutting edge is equal to or less than  
24 the width of the hole 16. This provides easy transfer of the cut bone into the  
25 space behind the blade and prevents clogging of the hole during the cutting  
26 operation.

27          As seen in Fig. 5, the hole 16 in this preferred embodiment is  
28 essentially normal to the long dimension of the blade so that the inner side of  
29 the cutting edge is essentially normal to the face of the blade which contacts



1 the bone. A slope 17 cooperates with hole 16 to define cutting edge 14.  
2 However, in use the blade is held at a slight angle to the bone 100, hence  
3 defined the working angle  $\alpha_w$ . The working angle of the instrument is  
4 equivalent to rake angle of the cutting edge with respect to the bone at the tip  
5 of the cutting edge 14, with an effective range of positive rake angles from  
6 about 5 - 50 degrees when the blade is mounted in the handle.

7 Novel features of the blade allow manual cutting of the bone, with  
8 several advantages over motorized or pneumatic tools. These advantages  
9 include decreased costs, decreased set-up time, and decreased heat generation  
10 to optimize bone cell survival.

11 The instrument is easily controlled in comparison to a osteotome or a  
12 gouge, where if these instruments disengage from the bone, they lunge into the  
13 tissue at the wound borders. With the pulling action of this design as shown  
14 as arrow P in Fig. 7A, it is unlikely that the patient would be harmed if the  
15 blade inadvertently disengages from the bone. Furthermore, cutting can be  
16 carried safely to the boundary of the exposed bone with the blade naturally  
17 tracking a straight line without a tendency to veer off.

18 The inner edge of the loop at its distal aspect 14 forms a positive rake  
19 angle with respect to the bone surface when the distal end is held in contact  
20 with, and at an acute angle to the bone. These various angles are illustrated in  
21 Fig. 6. Bone is an anisotropic material with varying requirements for cutting  
22 based on orientation. The rake angle ( $\alpha$ ) of the blade edge can be modified by  
23 the working angle ( $\alpha_w$ ) of the instrument to the bone surface. This allows  
24 adjustment of the cutting parameters of the blade for different bone properties.  
25 The Merchant analysis relates the effects of rake angle, depth, and material  
26 properties of isotropic materials as a function of a horizontal pulling force  
27 ( $P_x$ ) for cutting of a straight blade by:

28  
29

$$P_x = t_0 b t \cos (\beta - \alpha) / \sin \phi \cos (\phi + \beta - \alpha)$$

where:

$t_0$  = shear stress at failure on the shear zone (16,260 psi)

$\beta$  = friction angle =  $\arctan \mu$  ( $37^\circ$ )

$\alpha$  = tool rake angle ( $5^\circ - 50^\circ$ )

$\phi$  = shear plane angle ( $=34^\circ$ ,  $2\phi + \beta + \alpha = 90^\circ$ )

$b$  = work piece width (estimate 0.020 in)

$t$  = nominal chip thickness (depth of cut, estimate 0.005 in)

$\mu$  = friction coefficient between tool face and chip (0.75)

10

11 Substituting values into the equations with a rake angle of 30 degrees :

$$P_x = 16,260 \text{ psi} \cdot 0.020 \text{ in} \cdot 0.005 \text{ in} \cdot \cos (37^\circ - 30^\circ) / \sin 34^\circ \cos$$

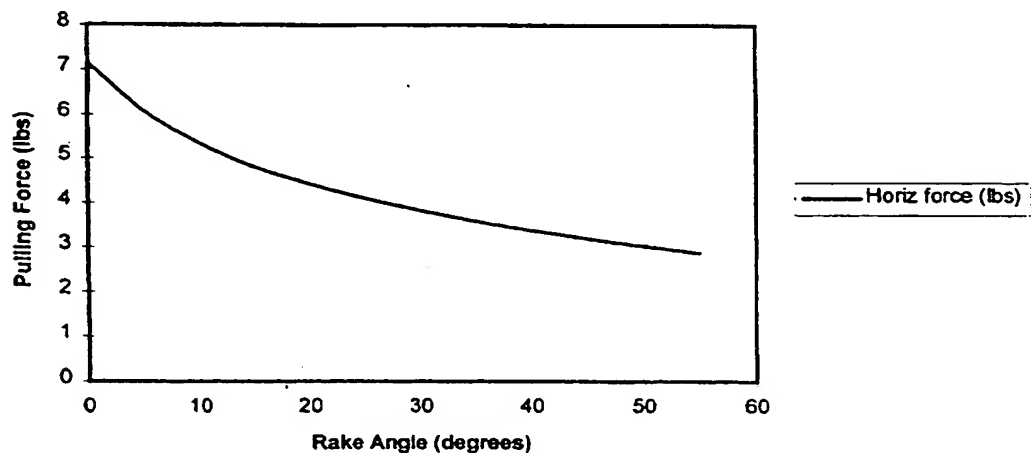
$$(34^\circ + 37^\circ - 30^\circ)$$

$$= 3.82 \text{ lbs}$$

15 This relationship is represented graphically for rake angles from 0-55

16 degrees as is illustrated in graph A below:

**Horizontal Force vs. Rake Angle**



**GRAPH A**

17  
18  
19

1           Theoretical results in comparison to experimental results are of limited  
2 agreement because of the anisotropic nature of bone. [Jacobs,CH, Pope, MH,  
3 Berry, JT, Hoaglund, F. A Study of the Bone Machining Process-Orthogonal  
4 Cutting J. Biomechanics, 7:131-136 1974]

5           As the working angle of the blade's curved loop is increased from zero  
6 degrees (full contact of the blade loop with the surface), only the point tangent  
7 to the loop's edge 14 remains in contact with the bone surface. Now only  
8 slight downward force (shown as arrow D) on the instrument is necessary the  
9 cause very high pressures at the interface between the blade and the bone. This  
10 allows the blade to penetrate and engage the bone and allows the cut to be  
11 initiated. In addition, this point contact allows the blade to engage flat,  
12 convex, and most concave bone surfaces. In comparison to a straight or flat  
13 blade design where contact surface is not influenced by working angle, contact  
14 area is large with higher forces required to penetrate and engage the surface.  
15 In addition, cutting of concave surfaces is greatly limited. Approximation of  
16 the maximum contact pressure(s) between the blade loop and the bone surface  
17 can be estimated from one derivation of the H. Hertz equations for a cylinder  
18 on a flat plate of equal modulus :

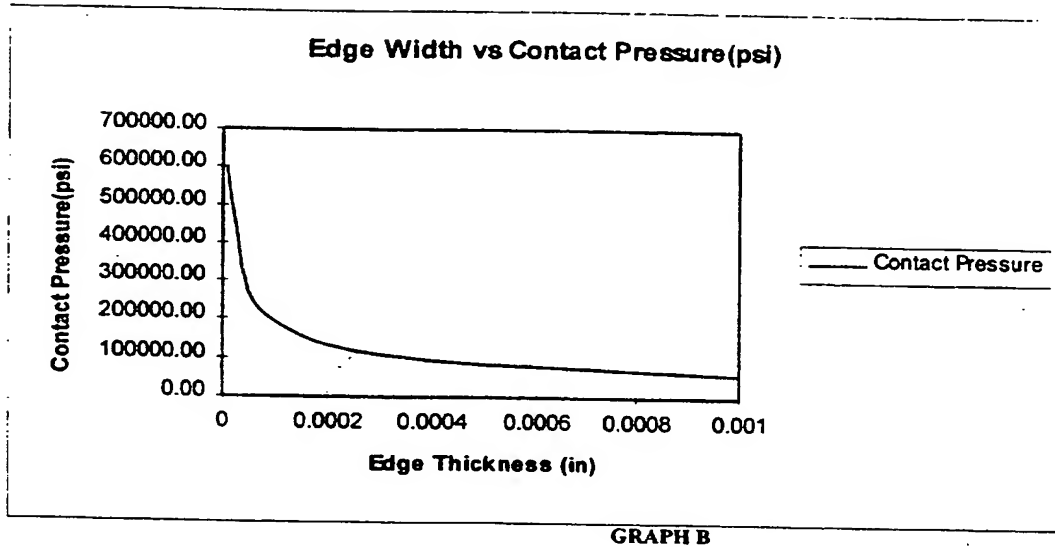
$$19 \quad s = 0.591 \sqrt{(P_l E / d_{cyl})}$$

20           where  $P_l$  = load per inch length,  $E$  = modulus of elasticity,  $d_{cyl}$  =  
21 diameter of cylinder. For a 1 lb. load on the blade edge 0.001 in width and  
22 0.25 in dia, and  $E$  for bone  $2.61 \times 10^6$  psi :

$$23 \quad s = 0.591 \sqrt{[1000 * 2.61 \times 10^6 / 0.25]} \\ 24 \quad = 60,386 \text{ psi}$$

25           The modulus of stainless steel is about 10 fold greater than cortical  
26 bone, with these contact pressures conservatively less than steel in contact  
27 with bone. Cortical bone, with ultimate tensile stress of 20,300 psi , would be  
28 indented and engaged by the blade.

Contact stress for a range of blade edge thickness are illustrated below in graph B:



The blade allows smooth, uniform cutting of bone with minimal chatter. After engagement of the blade into the bone surface, its positive rake angle further promotes deeper engagement of the blade without increase in normal force. The diving force  $F_d$  is a function of the pulling force parallel to the bone surface  $F_p$  and the working angle of the instrument  $\alpha_w$ :

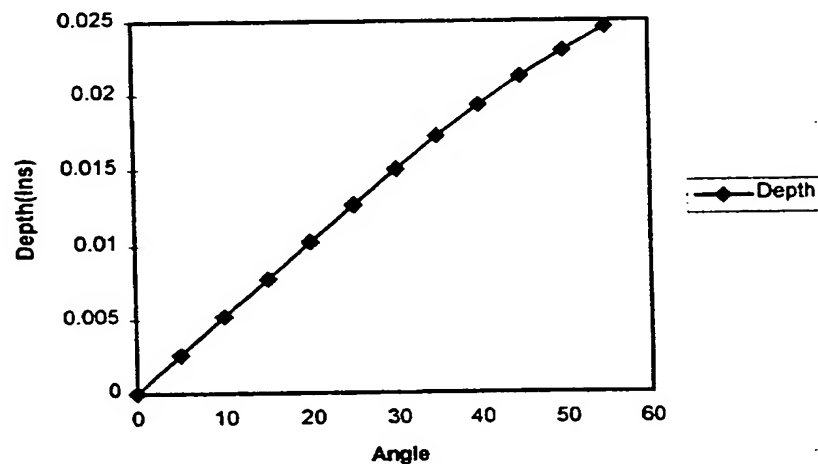
$$F_d = F_p \sin(\alpha_w)$$

The diving forces increase with the working angle of the instrument. Blade cutting depth reaches equilibrium. This is a function of the laterally decreasing rake angle from the central point of contact, the proximal edge 12A of the blade at the aperture 16, and a wedging effect caused by medial compression of the bone chip as it moves into the circular aperture 16. Geometrically, the aperture width  $w_a$  and working angle of the instrument  $\alpha_w$  limit the maximum depth of the dive  $d$ :

$$d = w_a \sin(\alpha_w)$$

- 1 Graphically, with an aperture width of 0.030 in, maximum cutting  
2 depth is shown in graph C:

**Max. Depth vs Working Angle**



**GRAPH C**

3  
4  
5

6 Anatomic bone surfaces present a terrain of variable contour, with  
7 access to these surfaces also limited by adjacent anatomic structures and  
8 overlying tissue. The curved loop shaped blade, Fig.5A, provides primary  
9 cutting along the longitudinal axis of the instrument. With the cutting edge at  
10 the distal end of the blade, this allows access under tissue flaps to the edge of  
11 the elevated periosteum. In addition, the blade can be moved laterally at its  
12 distal aspect to cut the bone surface in areas of limited access. Cutting now  
13 occurs in the more lateral and proximal positions of the loop 19.

14 The blade edge is hardened to approximately 58 Rockwell C (Brinell  
15 hardness~600 kg/mm<sup>2</sup>) to prolong its cutting life. Cortical bone has hardness  
16 80 Rockwell M (Brinell hardness ~30 kg/mm<sup>2</sup>). Hardness can be further  
17 enhanced with titanium nitride coating which also decreases the interface  
18 friction between the blade and the bone. The hollow grind of the blade relief at  
19 17 allows the edge profile to be thinner while optimizing the blade stiffness

1 with support above the edge. The edge is both ground and honed in a direction  
2 perpendicular to the edge to minimize areas of stress concentration that can  
3 occur as the blade thins to its edge.

4 Bone shavings 50 pass through the narrow aperture 16 and can be  
5 collected for eventual grafting purposes. The aperture is analogous to a one  
6 way valve, where the shavings easily pass through in their dense form before  
7 their shapes and orientations become randomized. This randomized form of  
8 the bone is favorable. It prevents the bone shavings from falling back through  
9 the aperture 16 and thus not being available for grafting. It allows the  
10 shavings to be collected without the use of vacuum which both desiccates and  
11 necroses the bone cells, and potentially contaminates the bone with saliva and  
12 soft tissue elements.

13 The bone shavings or chips have favorable properties with respect to  
14 their application as autogenous bone grafts. These include an increase in their  
15 surface area to volume ratio, an increase in the relative volume of bone, and a  
16 porosity that allows incorporation of blood and encourages vascular ingrowth  
17 and cell migration into the graft. The exposed collagen promotes coagulation  
18 of the blood elements and renders the graft in a favorable "mortar-like"  
19 consistency to be packed into the defect sites in the form of an osseous  
20 coagulum.

21 As mentioned previously, the distal end of the upper aspect of the  
22 blade incorporates a central ramp or tapered reduced thickness 13, with the  
23 proximal end of the ramp decreasing in thickness to where it ends at 12A  
24 adjacent the blade aperture 16. This reduced section is shown best in Fig 5B  
25 and has the function of providing a very thin blade section 12A immediately  
26 adjacent the rear of the hole 16. The blade thickness is maintained laterally  
27 with a ridge and sidewalls 15 adjacent to the ramp. This allows the blade loop  
28 to have the thickness required for strength, while providing a very short path  
29 through the aperture 16. This short passage reduces the chances of clogging.

1           The ramp 13 serves several additional functions. It provides an initial  
2 storage area for the shavings as they are collected. It provides an increase in  
3 the cross-sectional area of the reservoir that allows the handles external profile  
4 to be reduced in height and thus more accessible to constrained anatomic  
5 locations.

6           When the handle for the blade does not incorporate the storage area (as  
7 shown in Fig. 8a), the ramp 13 provides a seat for the bone as it is collected as  
8 shown in figs. 8a-b. A small collection chamber, not integral to the handle,  
9 can also be attached to the blade's upper surface as shown in Fig 8c. Finally, in  
10 concert with the handle chamber geometry, the chamber is designed with  
11 increasing cross-sectional area as one moves proximally, encouraging the  
12 chips to move into the handle proximally as the bone is collected.

13           The blade is preferably bowed longitudinally to create a spring that  
14 provides friction between the blade and the grooves 40 of the side wall 30 of  
15 the handle 20. This keeps the blade in the desired position until it  
16 intentionally needs to be shifted. With the variability in manufacturing, the  
17 longitudinal bow geometry allows a relatively large amount of deflection to be  
18 used, which makes dimensional variation in production inconsequential. Also,  
19 steel, as opposed to the plastic used in the handle, has a predictable modulus  
20 of elasticity that will not creep.

21           As seen best in Figs. 1 and 4, at the rear of the blade 12 there is  
22 provided a blade tab 18 which is adapted to be engaged to a lock button 26 on  
23 the end of the plunger 24 (see Figs. 1 and 3) which is mounted in the handle  
24 20 proximal of the blade 12. The extended length of the tab 18 from the  
25 cutting edge (as shown in Fig 4A) allows the tab 18 to transmit the raking  
26 force from the center of the handle where it has sufficient strength.  
27 Furthermore, manipulation of the blade is controlled safely away from the  
28 sharp edge. Finally, the extended length blade also serves as a 4th moveable  
29 wall of the collection chamber. This allows for a very compact design capable

1 of being used in tight places and allows easy access to the contents of the  
2 chamber.

3 As seen best in Figs. 8A-8E, for constrained anatomic sites, the blade  
4 may used with just a gripping handle attached to its proximal end. This leaves  
5 the upper surface of the blade exposed on its mid and distal aspects. This  
6 allows the blade access to more constrained anatomic locations and also  
7 allows the blade to be bent and offset to optimize its access to more specific  
8 anatomic locations. The blade can also be increased in thickness to provide  
9 more volume in its central ramped hollow to collect the bone shavings.

10 The details of the handle 20 are shown best in Fig. 2 wherein side wall  
11 30 and bottom wall 32 define a u-shaped space 32 as seen best in Fig. 2A.  
12 There are two sets of detents, the first set 36 are positioned to engage the tab  
13 on the rear end of the blade to prevent its moving beyond the end of the handle  
14 20. The second set 38 are positioned to engage the plunger tab 28 on the  
15 plunger 24 and retain the plunger in the position shown Fig. 1 with the lock  
16 button 26 in engagement with the blade tab.

17 The handle of the preferred embodiment serves multiple functions,  
18 integrating ergonomic handling and support of the blade, a storage  
19 compartment or reservoir of the collected bone, a site for combining additives  
20 as needed, and a means of delivering and dispensing the harvested bone at the  
21 recipient site. This integrated function also minimizes bone waste and possible  
22 contamination by minimizing handling of the bone and the accumulation of  
23 the graft material on surfaces such as hoses, filters, containers, etc.

24 The handle provides safe and clean storage of the harvested bone 50.  
25 After passing through the blade aperture 16 the bone enters a closed storage  
26 space formed by the handle in conjunction with the blade and the plunger. This  
27 space expands in cross-section area as it approaches the proximal aspect of the  
28 ramp, encouraging the bone shaves to move into the proximal aspect of the  
29 handle. The handle interior provides a trough shaped volume where the



1 contents can be inspected, additives incorporated, and any possible clogging of  
2 bone cleared. The plunger 24 can be advanced to consolidate the harvested  
3 bone 50 with the blade fully forward. With the blade partially retracted, the  
4 plunger advances the graft material to the distal aspect of the handle to provide  
5 a streamline trough or channel to deliver bone to the recipient site 102.

6 The preferred profile for the forward portion of the handle is  
7 minimized by transmitting the raking force from the handles center, its thicker  
8 and stronger portion. Only a small amount of handle material is required for  
9 sufficient strength to carry the normal load to the nose of the handle. This  
10 results in a low instrument profile, capable of getting into anatomic spaces of  
11 limited dimension. A single pair of grooves 40 guide and retain both the blade  
12 and the plunger. This helps to minimize the overall height of the handle.

13 The handle is preferably fabricated with a clear plastic. This allows the  
14 bone shavings to be monitored as they are cut, providing immediate feedback  
15 of bone collection. The total volume of bone collected can be monitored with  
16 respect to known volume gradations on the handle that inform the surgeon  
17 when an adequate volume of bone has been collected.

18 When the blade is used such that middle and distal portions are  
19 exposed, a gripping handle 60 is secured to the proximal end of the blade to  
20 facilitate handling of the blade as shown in Figs 8A and 8C-8E. The handle  
21 60 is long and round for secure gripping in the hand and has a slot 62 to accept  
22 the blade and a rotatable, tightening mechanism 64 to secure the blade in the  
23 handle. Also, as shown in Fig. 8F, the blade may be bent at 101, e.g., to  
24 facilitate access to tight spots.

25 If desired, the blade may be formed into an elongated "cup" shape, i.e.  
26 as shown in Fig. 8B, and a clear or transparent cover 66 fitted over the top of  
27 the "cup" so as to permit the user to view the progress of bone collection.

1           The plunger 24 serves two functions; 1) to consolidate and advance the  
2 bone into the distal end of the chamber, and 2) it provides a locking  
3 mechanism to secure the blade in its forward position .

4           The plunger head 42 provides the proximal wall of the storage  
5 chamber. The plunger is advanced by releasing the locking button 26 which  
6 secures both the plunger and the blade in place for cutting and collection. The  
7 head of the plunger is held in the track distally by riding under the blade. The  
8 proximal end is constrained in the same track 40 that the blade rides in and  
9 translates forward to a small stop at the forward end of the handle.

10          Referring to Fig. 3, the details of the plunger are shown in top view  
11 and sectional view wherein the lock button 26 as shown as being mounted on a  
12 cantilever arm 46 enabling it to be moved towards the bottom of the plunger.  
13 The side edges of the plunger are free of the grooves 40 in the side wall of the  
14 handle. The sloping surface 44 on the detent arm 40 engages the proximal end  
15 of the blade to press the blade tab 18 against the detents 36, thus locking the  
16 blade in correct position.

**Claims**

1

2           1. An instrument for harvesting bone comprising an elongate body  
3 (20) having a proximal end and distal end; said body serving as a handle for  
4 supporting a blade (12) so that the blade can be held at an acute angle with  
5 respect to a bone from which bone shavings are to be harvested;

6           said blade having a cutting structure (14) adjacent its distal end;  
7           the cutting edge of the structure being defined by a curved hole (16)  
8 adjacent the distal end of the blade and a tapered curved convex surface  
9 forming the distal end of the blade.

10          2. The instrument in claim 1, wherein the blade has a loop shaped  
11 cutting structure and the inner edge of the loop at its distal end forms a  
12 positive rake angle ( $\alpha$ ) with respect to the bone surface when said distal end is  
13 held in contact with , and at an angle to, the bone.

14          3. The instrument of claim 1, wherein the blade has a reduced  
15 thickness immediately adjacent the inner edge of the curved hole (16).

16          4. The instrument in claim 3, wherein said reduced thickness is less  
17 than the radial width of the curved hole (16).

18          5. The instrument in claim 2, wherein the relative rake angle ( $\alpha$ ) of the  
19 cutting edge with respect to the bone decreases as the contact area extends  
20 proximal along the curved edge.

21          6. The instrument in claim 3, wherein the outer section of the blade  
22 engaging surface is of full thickness to provide a force-transmitting structure  
23 for the end (14) of the curved blade.

24          7. The instrument of claim 3, wherein the reduced thickness  
25 immediately adjacent the inner edge of the curved hole (16) is a ramp-like  
26 depression centrally positioned in the blade, with its sidewall retaining the  
27 blades full thickness.

1           8. The instrument of claim 7, wherein the overall thickness of the  
2 blade (12) is increased, where the central depression (13) then provides a  
3 storage area for the bone shavings.

4           9. The instrument of claim 2, wherein the middle portion of the blade  
5 (12) has various degrees of bends or offsets to facilitate access to difficult  
6 surfaces.

7           10. The instrument in claim 8, wherein a hollow structure (32) is  
8 attached to the blade over the central depression to provide a storage chamber  
9 of greater volume for the bone shavings.

10           11. The instrument of claim 1, wherein the blade has a tab (28) at its  
11 proximal end for transmitting cutting forces to the central portion of the  
12 handle.

13           12. The instrument of claim 1, wherein the blade (12) and the handle  
14 (60) are one piece.

15           13. The instrument of claim 14, wherein a plunger (26) is incorporated  
16 into the handle to cause the bone shavings in the storage compartment to be  
17 consolidated and dispensed at the distal end of the instrument.

18           14. An instrument for harvesting bone comprising an elongate body  
19 (20) having a proximal end and distal end; said body serving as a handle for  
20 supporting a blade (12) so that the blade can be held at an acute angle with  
21 respect to a bone from which bone shavings are to be harvested;

22           said blade having a cutting structure (14) adjacent its distal end;  
23           the cutting edge of the structure being defined by a curved hole (16)  
24 adjacent the distal end of the blade and a tapered curved convex surface  
25 forming the distal end of the blade;

26           said blade and handle cooperating to provide a storage space (24)  
27 adjacent the distal end of the blade for receiving harvested bone from the  
28 cutting structure.

1           15. The instrument in claim 14, wherein the handle (20) is of an  
2 ergonomic streamline shape, with a shallow distal profile for accessing greatly  
3 narrowed spaces.

4           16. The instrument in claim 13, wherein said handle (20) is channel  
5 shaped, thus creating a central storage space (32) and allowing for a moveable  
6 4th wall to access said space.

7           17. The instrument in claim 16, wherein a track runs along the upper  
8 aspect of each side of the channel to secure and allow movement of the blade  
9 (12) and plunger (24) mechanism.

10          18. The instrument of claim 14, wherein the handle is composed of a  
11 clear plastic (66) that provides visual feedback of the progress in collecting the  
12 bone shavings (50).

13          19. The instrument of claim 18, wherein graduations are present to  
14 provide indication of the volume of material (50) collected.

15          20. The instrument of claim 14, wherein the channel defined by the  
16 blade and handle is expanding in cross-sectional area as one proceeds from the  
17 distal to proximal aspect of the handle to encourage flow of bone chips (50)  
18 into the handle and away from the blade edge (14).

19          21. The instrument of claim 17, wherein adjacent to said track are  
20 dentents (36) and/or protrusions that provide stops for positioning the blade  
21 and the plunger.

22          22. The instrument of claim 13, wherein the plunger also provides a  
23 locking mechanism (42,44) that is self adjusting for manufacturing variation to  
24 firmly secure the blade in its distal position when the instrument is cutting  
25 function.

26          23. The instrument of claim 14, wherein the blade forms the fourth  
27 wall (42) of the storage chamber of the handle.

28          24. The instrument of claim 17, wherein the blade (12) is bowed  
29 longitudinally to provide friction for the blade in the track.

- 1           25. A blade for use in an instrument for harvesting bone;  
2           the blade (12) having a cutting structure adjacent the distal end;  
3           the blade having a reduced thickness (13) immediately adjacent the  
4           inner edge of the curved hole to hold bone;  
5           the blade having a loop shaped cutting structure (14) and the inner edge  
6           of the loop at its distal end forms a positive rake angle ( $\alpha$ ) with respect to the  
7           bone surface when said distal end is held in contact with, and at an angle to,  
8           the bone;  
9           the ends of the cutting edge having a reduced rake angle with respect to  
10          an engaged bone surface during the movement of the surface in the direction  
11          of the long dimension of the instrument.
- 12          26. A blade for use in an instrument for harvesting bone;  
13          the blade (12) having a cutting structure (14) adjacent the distal end;  
14          the cutting edge of the structure being defined by a curved hole (16)  
15          adjacent the distal end of the blade and a tapered curved convex surface  
16          forming the distal end of the blade;  
17          the blade having a loop shaped cutting structure and the inner edge of  
18          the loop at its distal end forming a positive rake angle ( $\alpha$ ) with respect to the  
19          bone surface when said distal end is held in contact with, and at an angle to,  
20          the bone;  
21          the ends of the cutting edge having a reduced rake angle with respect to  
22          an engaged bone surface during the movement of the surface in the direction  
23          of the long dimension of the instrument;  
24          the cutting edge of the structure being defined by a curved hole (16)  
25          adjacent the distal end of the blade and a tapered curved convex surface  
26          forming the distal end of the blade.
- 27          27. A blade for use in an instrument for harvesting bone;  
28          said blade being adapted to provide a storage space (13) for receiving  
29          harvested bone;

1           the blade having a cutting structure (14) adjacent the distal end;  
2           the cutting edge of the structure being defined by a curved hole (16)  
3 adjacent the distal end of the blade and a tapered curved convex surface  
4 forming the distal end of the blade;  
5           the blade having a reduced thickness immediately adjacent the inner  
6 edge of the curved hole.

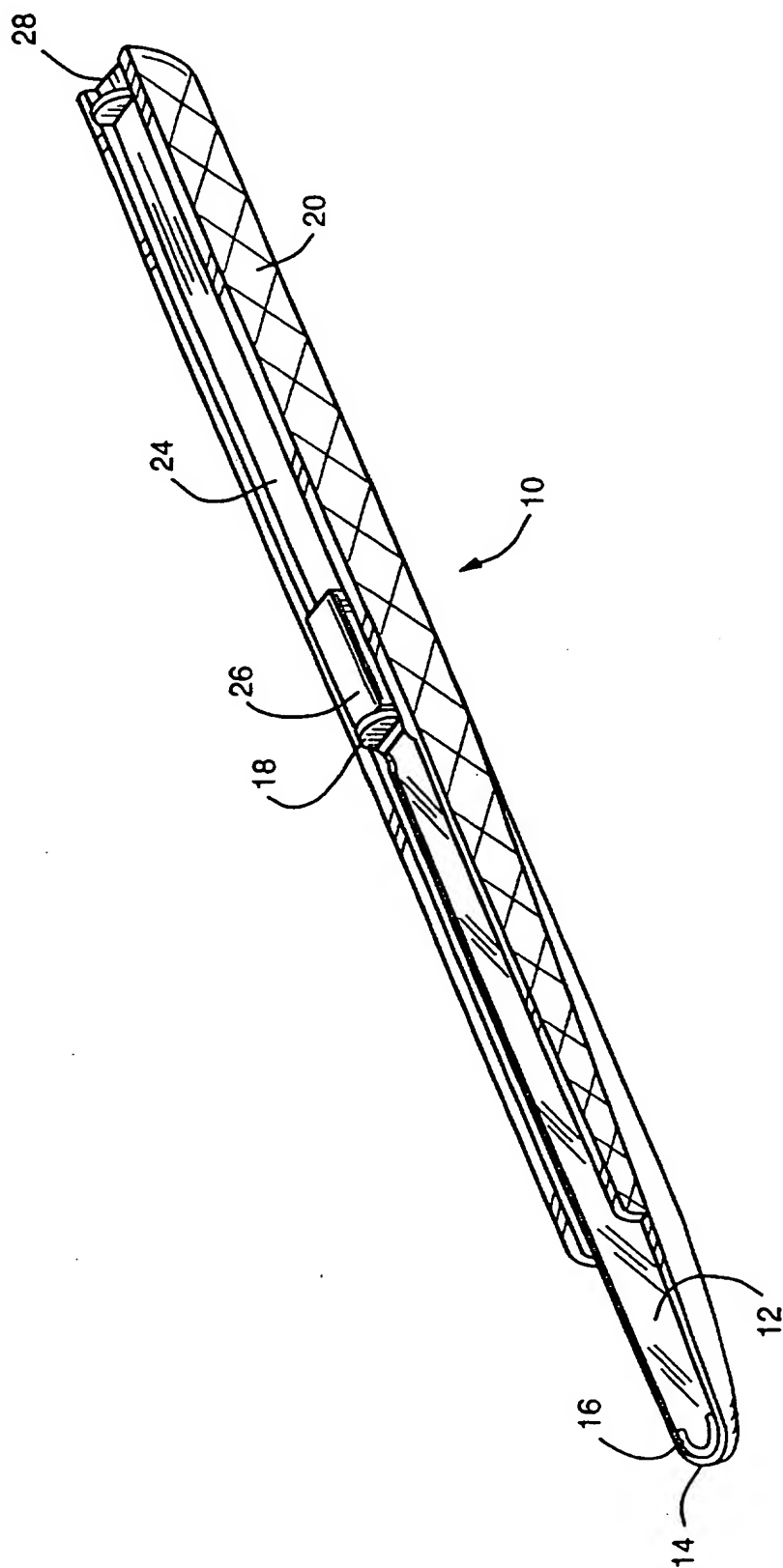
7           28. The instrument of claim 13, wherein a lock button (26) is provided  
8 on the distal end of the plunger, the distal end of the lock button engaging the  
9 proximal end of the blade.

10          29. The instrument of claim 28, wherein the lock button (26) is  
11 carried on the end of a spring arm (46) to permit compression of the lock  
12 button into the groove to release the blade tab to permit the blade to be  
13 withdrawn in the proximal direction and to permit the plunder to be pushed  
14 towards the distal end of the handle to contact bone particles (50) stored in the  
15 handle.

16          30. The instrument of claim 28, wherein the lock button (26) is  
17 positioned proximally of the pusher.

18

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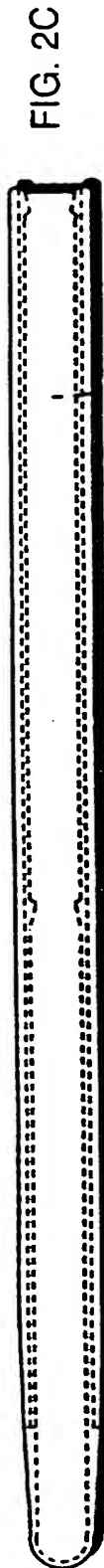


FIG. 2C

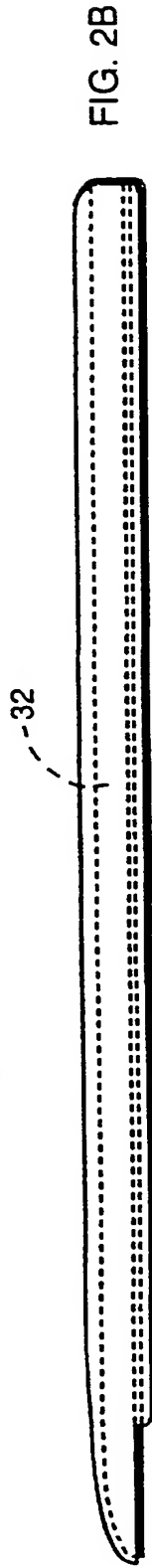


FIG. 2B

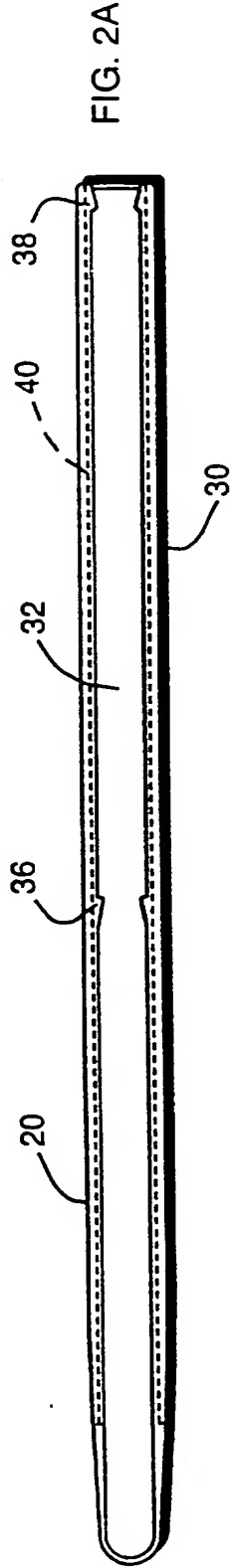


FIG. 2A

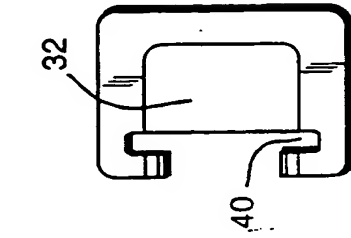


FIG. 2D

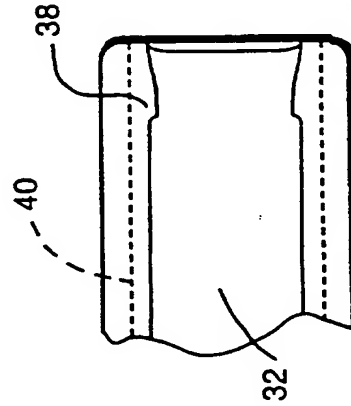


FIG. 2E

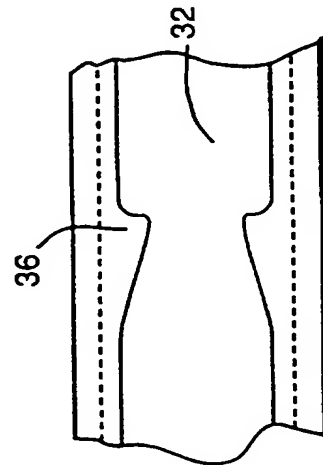
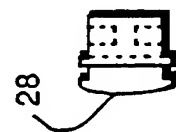
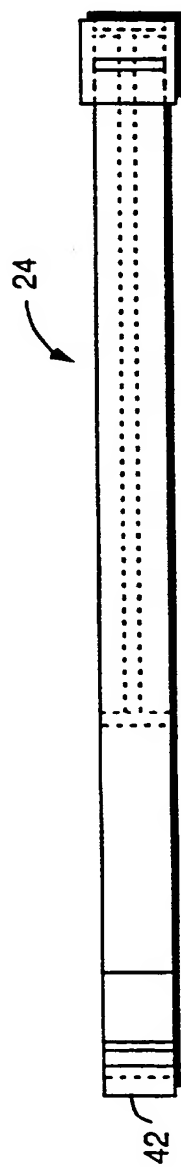
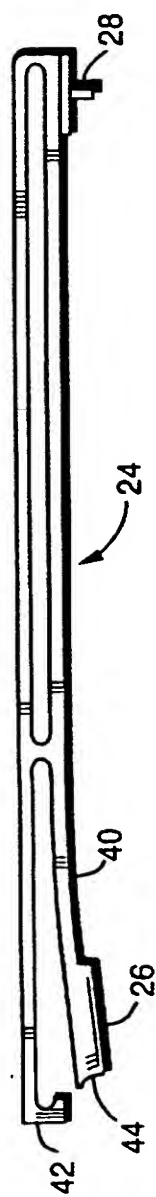
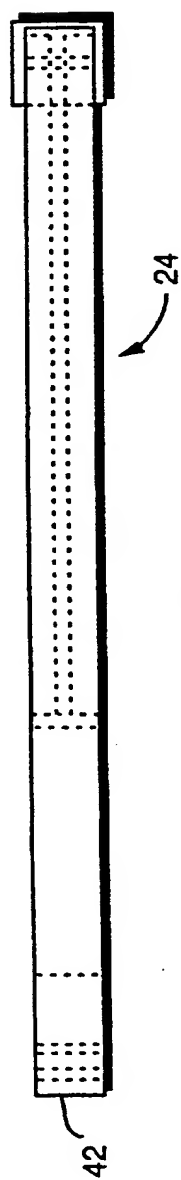


FIG. 2F



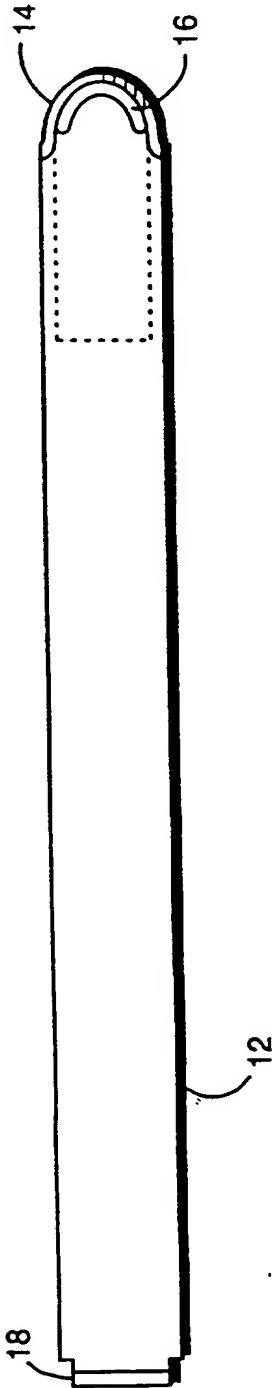


FIG. 4A



FIG. 4C



FIG. 4B

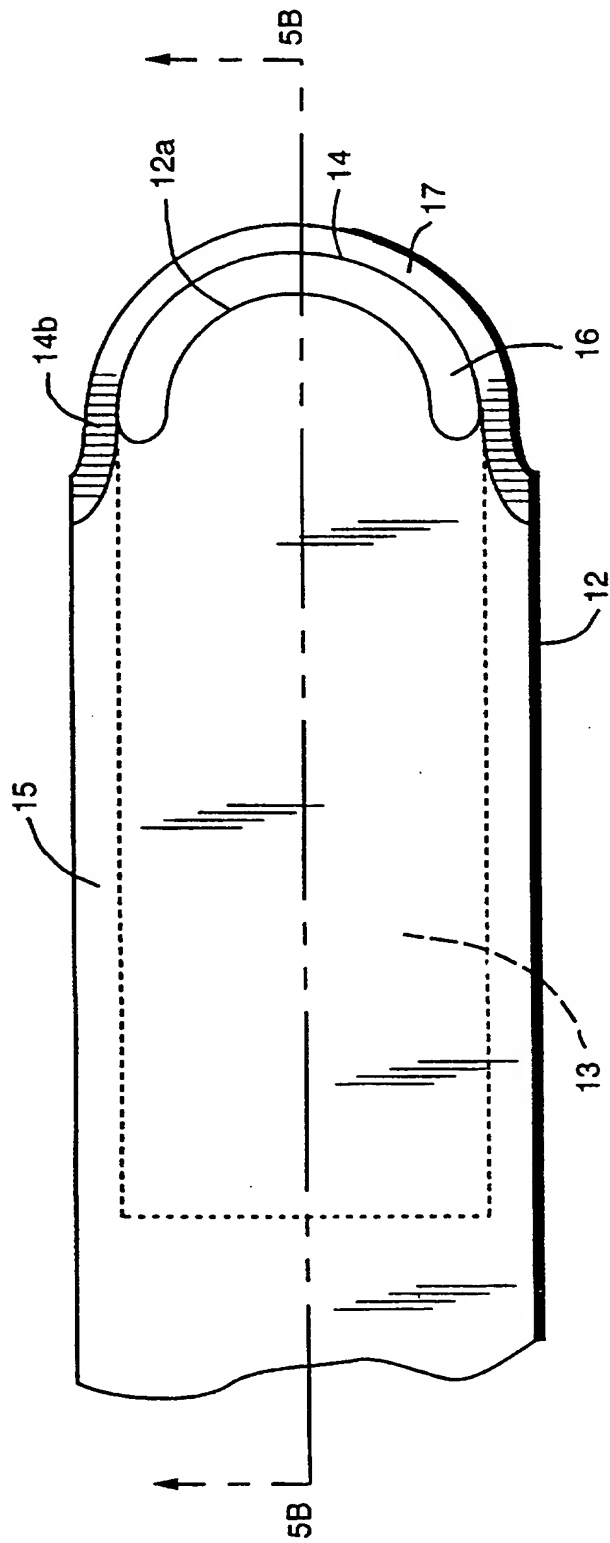


FIG. 5A

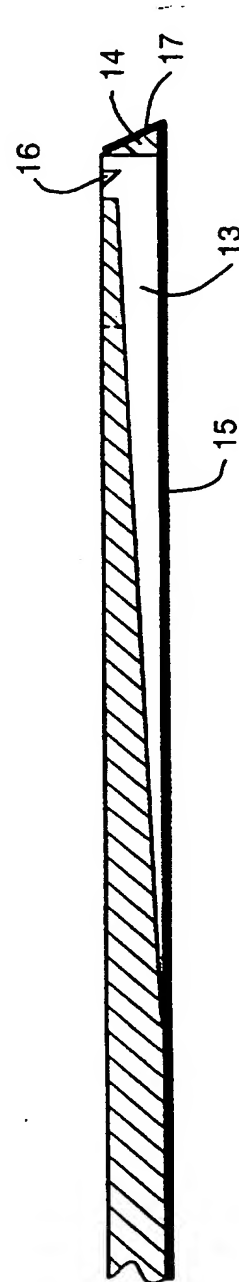


FIG. 5B

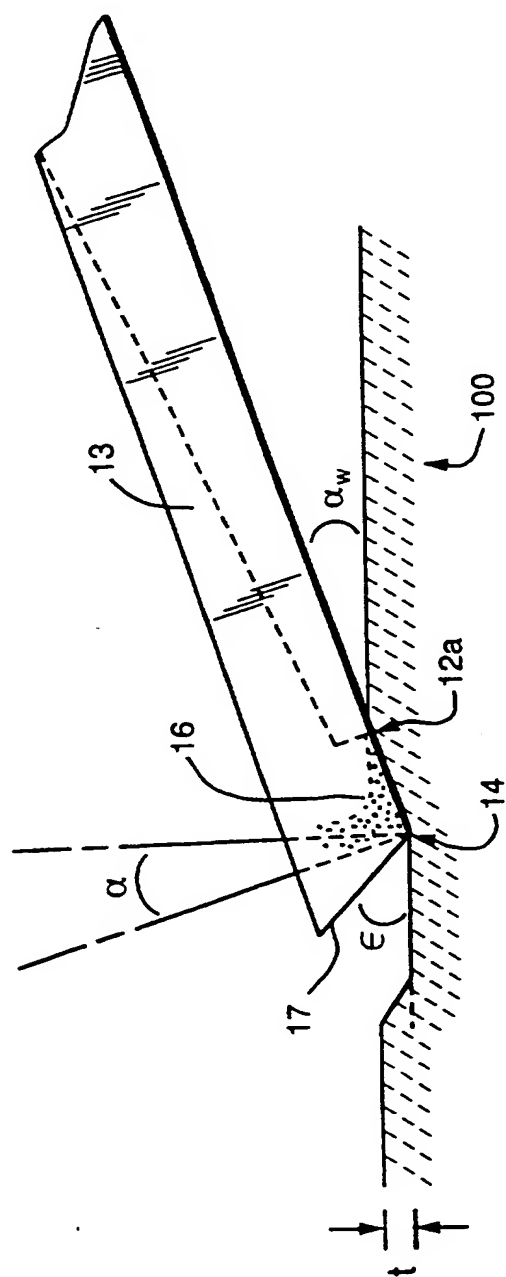


FIG. 6

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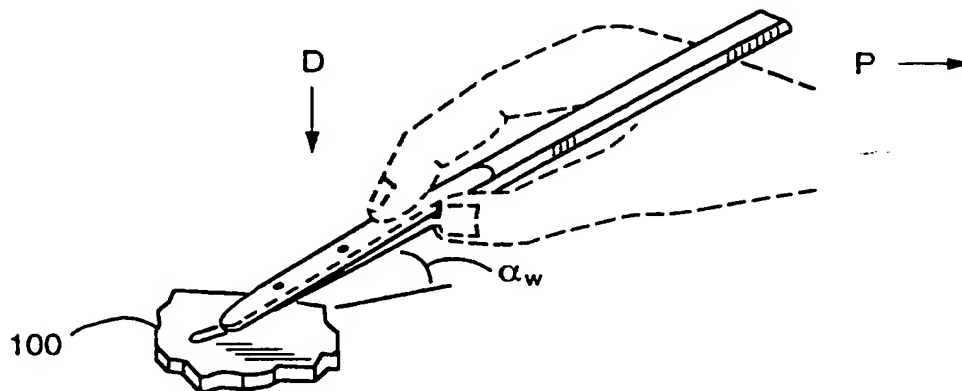


FIG. 7A

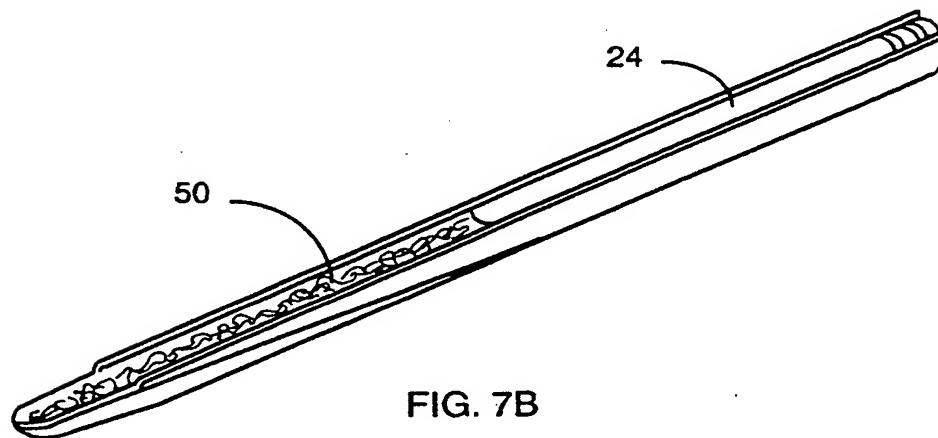


FIG. 7B

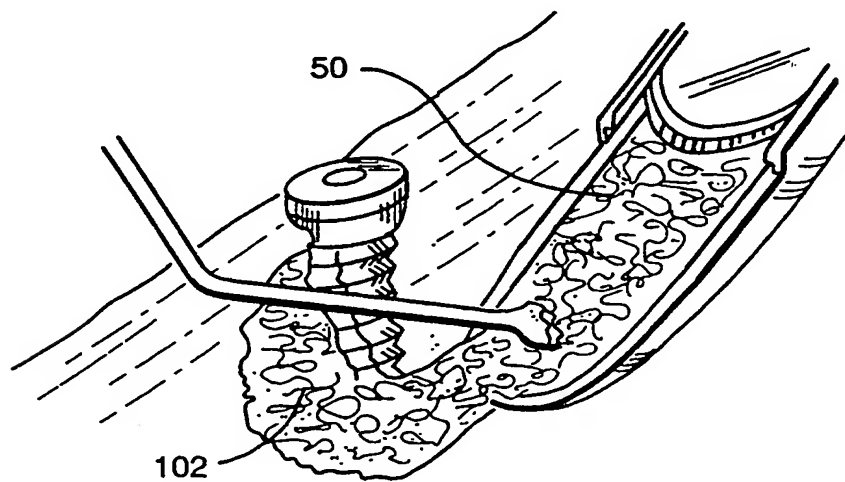
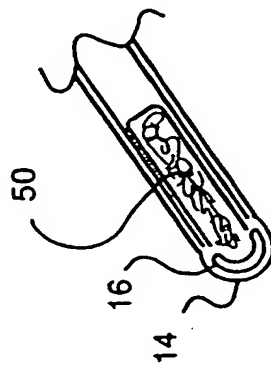
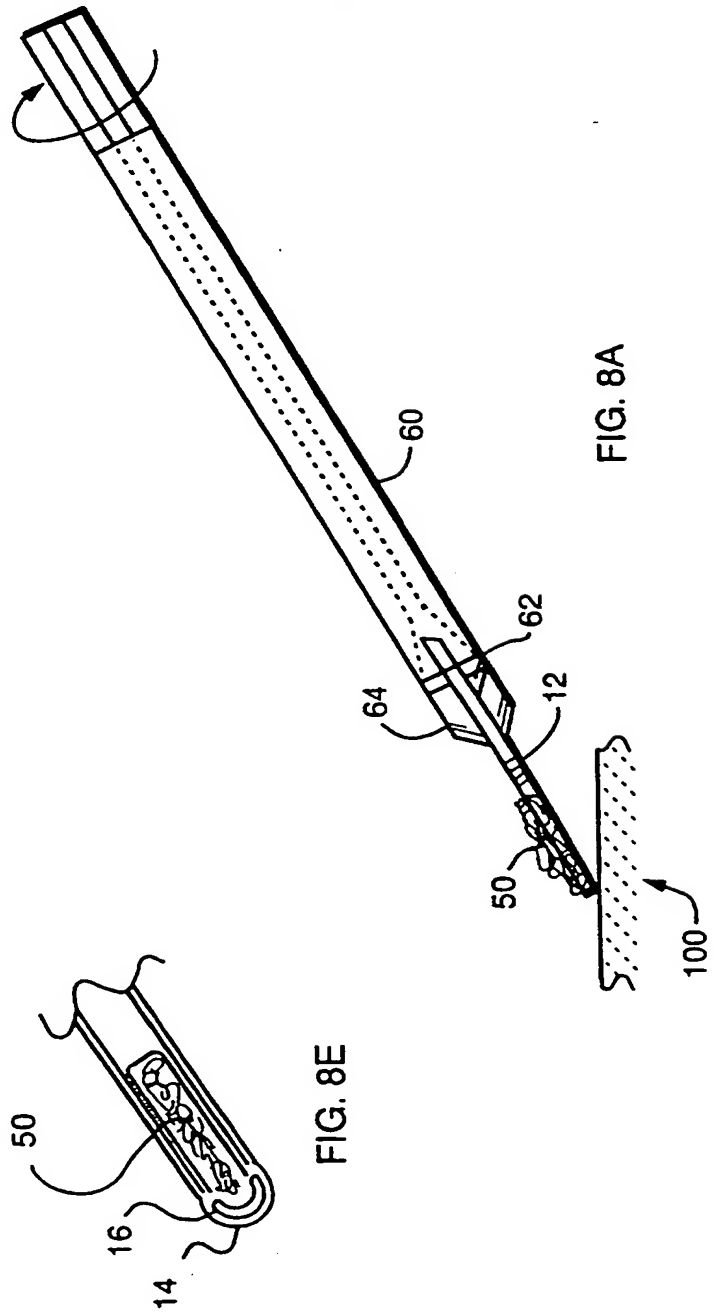
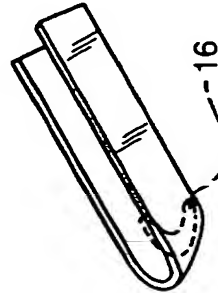
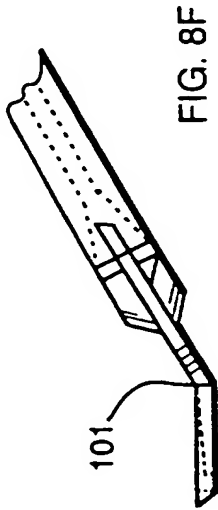
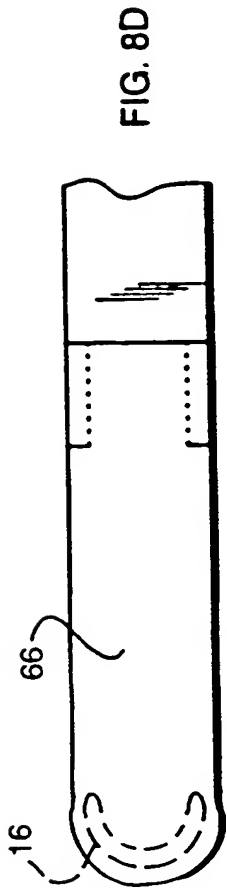


FIG. 7C

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# INTERNATIONAL SEARCH REPORT

Inter. Application No  
PCT/US 96/15030

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61B17/32 A61B10/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,2 876 777 (G. KEES ,JR) 10 March 1959  see column 2, line 19 - line 65 ---	1,2,5, 12,14, 15,25-27
A	US,A,4 221 222 (DETSCH STEVEN G) 9 September 1980 see abstract -----	1,12,14, 15,25,26

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

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- \* "E" earlier document but published on or after the international filing date
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Date of the actual completion of the international search

6 January 1997

Date of mailing of the international search report

10.01.97

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentaan 2  
NL - 2280 HV Rijswijk  
Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl,  
Fax (+ 31-70) 340-3016

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Vereist, P



# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 96/15030

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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# ANHANG ZUM EUROPÄISCHEN RECHERCHENBERICHT ÜBER DIE EUROPÄISCHE PATENTANMELDUNG NR.

EP 01 12 5715

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten europäischen Recherchenbericht angeführten Patentedokumente angegeben.  
Die Angaben über die Familienmitglieder entsprechen dem Stand der Datei des Europäischen Patentamts am  
Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

10-12-2001

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